



UNITED STATES DEPARTMENT OF COMMERCE **Patent and Trademark Offic**

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Washington, D.C. 20231

VB

12/06/99

APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 09/147,405 04/01/98 GUSS В REF/GUSS/P33 **EXAMINER** HM12/1206 BACON & THOMAS LEE, L 625 SLATERS LANE 4TH FLOOR PAPER NUMBER **ART UNIT** ALEXANDRIA VA 22314-1176 1645 DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Art Unit: 1645

DETAILED ACTION

Nucleotide and /or Amino acid Sequence Disclosures

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. See the attached Raw Sequence Listing Error Report. Applicants are reminded that all the sequences disclosed in the application need to be comply with the requirements. It is noted that the sequences in the claims and figures in this application fail to comply with the requirements of 37 CFR 1.821 through 1.825.

APPLICANT IS GIVEN A ONE MONTH EXTENDABLE PERIOD WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Art Unit: 1645

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 and 25, drawn to a protein or polypeptide.

Group II, claim(s) 2-11 and 26, drawn to recombinant DNA molecule, expression system, and method for producing the protein.

Group III, claim(s) 12-14, drawn to the use of a protein from staphylococci to block the adherence of staphylococci to surfaces with immobilized fibrinogen.

Group IV, claim(s) 15, drawn to the use of a protein from staphylococci to isolate fibringen.

Group V, claim(s) 16, drawn to the use of a gene to detect the presence of S. epidermidis.

Group VI, claim(s) 17, drawn to antibodies.

Group VII, claim(s) 18, drawn to the use of antibodies for diagnostic purpose.

Group VIII, claim(s) 19 and 29, drawn to the use of antibodies for therapeutic purposes.

Group IX, claim(s) 20-22, drawn to the use of antibodies to block the adherence of Staphylococci.

Art Unit: 1645

Group X, claim(s) 23-24 and 27, drawn to the use a protein from Staphylococci as an immunogen.

Group XI, claim(s) 28, drawn to a method of active immunization administering the DNA sequence.

The inventions listed as Groups I-XI do not relate to a single general inventive concept 3. under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-XI appears to be that they relate to a polypeptide designated as a protein or a polypeptide having fibrinogen binding activity from a coagulasenegative staphylococci strain.

However, Heimburger et al (US 4,245,039, Jan 13, 1991) teach a protein (clumping factor) having fibrinogen binding activity from a coagulase-negative staphylococci strain, staphylococcus aureus Newman D2C (column 2, lines 18-26).

Therefore, the technical feature linking the inventions of groups I-XI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Art Unit: 1645

The special technical feature of Group I is considered to be a a protein or polypeptide or a vaccine composition characterized as the protein having fibrinogen binding activity from a coagulase-negative staphylococci strain.

The special technical feature of Group II is considered to be a recombinant DNA molecule, expression system, and method for producing the protein.

The special technical feature of Group III is considered to be the use of a protein from staphylococci to block the adherence of staphylococci to surfaces with immobilized fibrinogen.

The special technical feature of Group IV is considered to be the use of a protein from staphylococci to isolate fibrinogen.

The special technical feature of Group V is considered to be the use of a gene to detect the presence of S. epidermidis.

The special technical feature of Group VI is considered to be antibodies raised against the protein.

The special technical feature of Group VII is considered to be the use of antibodies for diagnostic purpose.

The special technical feature of Group VIII is considered to be the use of antibodies for therapeutic purposes.

The special technical feature of Group IX is considered to be the use of antibodies to block the adherence of Staphylococci.

Art Unit: 1645

The special technical feature of Group X is considered to be the use a protein from Staphylococci as an immunogen.

The special technical feature of Group XI is considered to be a method of active immunization administering the DNA sequence.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee, M.D., Ph.D. whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995.

Li Lee, M.D., Ph.D. November 24, 1999

ANTHONY C. CAPUTA SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600

Page 7

Art Unit: 1645

Raw Sequence Listing Error Summary

		1/1/21/06
	ERROR DETECTED	SUGGESTED CORRECTION SERIAL NUMBER: 09/147,405
ATTN:	NEW RULES CASES: P	LEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE
; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ;	Wrapped Nucleics	The number/text at the end of each line "wrapped" down to the next line.
	• •	This may occur if your file was retrieved in a word processor after creating it.
		Please adjust your right margin to .3, as this will prevent "wrapping".
	Marines	The amino acid number/text at the end of each line "wrapped " down to the next line.
<u>'</u> —	Wrapped Aminos	This may occur if your file was retrieved in a word processor after creating it.
		Please adjust your right margin to .3, as this will prevent "wrapping".
3	Incorrect Line Length	The rules require that a line not exceed 72 characters in length. This includes spaces.
	Misaligned Amino Acid	The numbering under each 5th amino acid is misaligned. This may be caused by the use of tabs
·—	Numbering	between the numbering. It is recommended to delete any tabs and use spacing between the numbers.
	1129	\cdot
5	Non-ASCII	This file was not saved in ASCII (DOS) text, as required by the Sequence Rules.
		Please ensure your subsequent submission is saved in ASCII text so that it can be processed.
2	Variable Length	Sequence(s) contain n's or Xaa's which represented more than one residue.
·	Vallable Lengul	As per the rules, each n or Xaa can only represent a single residue.
		Please present the maximum number of each residue having variable length and
		indicate in the (ix) feature section that some may be missing.
_	D-1	A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid
′ —	Patentin ver. 2.0 "bug"	sequence(s) Normally, Patentin would automatically generate this section from the
		previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section
		to the subsequent amino acid sequence.
⁸	Skipped Sequences	Sequence(s) missing. If intentional, please use the following format for each skipped sequence:
	(OLD RULES)	(2) INFORMATION FOR SEQ ID NO:X: (I) SEQUENCE CHARACTERISTICS:(Do not insert any headings under "SEQUENCE CHARACTERISTICS")
	·	(xi) SEQUENCE DESCRIPTION:SEQ ID NO:X:
		This sequence is intentionally skipped
		Please also adjust the "(iii) NUMBER OF SEQUENCES:" response to include the skipped sequence(s).
9	Skipped Sequences	Sequence(s) missing. If intentional, please use the following format for each skipped sequence.
	(NEW RULES)	<210> sequence id number
i		<400> sequence id number
- 1		000
/	Use of n's or Xaa's	Use of n's and/or Xaa's have been detected in the Sequence Listing.
<u> </u>	(NEW RULES)	Use of <220> to <223> is MANDATORY if n's or Xaa's are present.
	(NEW NOCES)	In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.
1	Use of <213>Organism	Sequence(s) are missing this mandatory field or its response.
	(NEW RULES)	
2	Us of <220>Feature	Sequence(s) are missing the <220>Feature and associated headings.
	(NEW RULES)	Use of <220> to <223> is MANDATORY if <213>ORGANISM is "Artificial" or "Unknown"
		Please explain source f genetic material in <220> to <223> section.
		(See "Federal Register," 6/01/98, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of new Rules)
3	Patentle 6 6 7 6	Please d not use "C py to Disk" function of Patentin versi n 2.0. This causes a corrupted
-	Patentin ver. 2.0 "bug"	file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing).
		Instead, please use "File Manager" or any other means to copy file to floppy disk.
		AKS-Biotechnology Systems Branch- 5/15/99

PAGE: 1

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RAW SEQUENCE LISTING
PATENT APPLICATION US/09/147,405

DATE: 11/15/1999

TIME: 10:51:16

Input Set: I147405.RAW

This Raw Listing contains the General Information Section and up to first 5 pages.

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RAW SEQUENCE LISTING DATE: 11/15/1999
PATENT APPLICATION US/09/147,405 TIME: 10:51:16 PAGE: 2

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DATE: 11/15/1999 TIME: 10:51:16 RAW SEQUENCE LISTING 3 PAGE:

PATENT APPLICATION US/09/147,405

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DATE: 11/15/1999 PATENT APPLICATION US/09/147,405 TIME: 10:51:16

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PAGE: 5 RAW SEQUENCE LISTING DATE: 11/15/1999

PATENT APPLICATION US/09/147,405 TIME: 10:51:16

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234		-1-				165		-2 -			170		•			175		
235		Leu	Pro	Ile	Asn		Tyr	Glu	Asn	Lys	Ala	Arg	Pro	Leu	Ser	Thr	Thr	
236					180		- 4 -			185		_			190			
237		Ser	Ala	Gln		Ser	Ile	Lys	Arg	Val	Thr	Val	Asn	Glñ	Leu	Ala	Ala	
238				195				•	200					205				
239		Glu	Gln		Ser	Asn	Val	Asn		Leu	Ile	Lys	Val	Thr	Asp	Gln	Ser	
240			210					215				-	220		_			
241		Ile			Gly	Tyr	Asp	Asp	Ser	Glu	Gly	Val	Ile	Lys	Ala	His	Asp	
242		225			-	-	230	_			=	235					240	
243				Asn	Leu	Ile	Tyr	Asp	Val	Thr	Phe	Glu	Val	Asp	Asp	Lys	Val	
244						245					250					255		

VERIFICATION SUMMARY
ATENT APPLICATION US/09/14,405

DATE: 11/15/1999
TIME: 10:51:16

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38 W "N" or "Xaa" used: Feature required gantcngant cnganagn

Application No.: 09/147,405

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

	 This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
	This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
	3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
X	4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
	5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
	6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
	7. Other:
Аp	plicant Must Provide:
X	An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
X	An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
X	A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).
,_	was dispersed in a compliance to those requirements, please contact:

For questions regarding compliance to these requirements, please contact:

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